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Patent
Attorney's Docket No. 028870-080

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

UTILITY PATENT
APPLICATION TRANSMITTAL LETTER

Box PATENT APPLICATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed for filing is the utility patent application of Sean Lee and James L. Meyers for
BIOACTIVE GLASS TREATMENT OF INFLAMMATION IN SKIN CONDITIONS.

Also enclosed are:

- ☐ ___ sheet(s) of ☐ formal ☐ informal drawing(s);
- ☐ a claim for foreign priority under 35 U.S.C. §§ 119 and/or 365 ☐ is hereby made to _
filed in _ on _ ☐ in the declaration;
- ☐ a certified copy of the priority document;
- ☐ a Constructive Petition for Extensions of Time;
- ☒ 1 verified statement(s) claiming small entity status;
- ☒ an Assignment document;
- ☐ an Information Disclosure Statement; and
- ☐ Other: _.

The declaration of the inventor(s) ☒ also is enclosed ☐ will follow.

The filing fee has been calculated as follows ☐ and in accordance with the enclosed
preliminary amendment:

CLAIMS					
	NO. OF CLAIMS		EXTRA CLAIMS	RATE	FEE
Basic Application Fee					\$ 790.00
Total Claims	9	MINUS 20 =	0	x \$22 =	.00
Independent Claims	2	MINUS 3 =	0	x \$82 =	.00
If multiple dependent claims are presented, add \$270.00					.00
Total Application Fee					\$790.00
If verified statement claiming small entity status is enclosed, subtract 50% of Total Application Fee					\$395.00
Add Assignment Recording Fee of \$40.00 if Assignment document is enclosed					\$40.00
TOTAL APPLICATION FEE DUE					\$435.00

09012272 012398

☐ A check in the amount of \$_____ is enclosed for the fee due.

☒ Charge \$ 435.00 to Deposit Account No. 02-4800 for the fee due.

Please address all correspondence concerning the present application to:

Ronald L. Grudziecki
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, Virginia 22313-1404.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Allen R. Baum
Allen R. Baum
Registration No. 36,086

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: January 23, 1998

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Jennifer Pate
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UNITED STATES PATENT APPLICATION

for

**BIOACTIVE GLASS TREATMENT OF INFLAMMATION
IN SKIN CONDITIONS**

of

Sean Lee and Jim Meyers

Burns, Doane, Swecker & Mathis L.L.P.

The George Mason Building

Washington & Prince Streets

Post Office Box 1404

Alexandria, Virginia 22313-1404

"Express Mail" mailing label No. EE060757680US
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060469-04398

BIOACTIVE GLASS TREATMENT OF INFLAMMATION

IN SKIN CONDITIONS

FIELD OF THE INVENTION

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This invention relates to a topical treatment and composition which may be applied to mitigate inflammatory symptoms such as burning, redness, itching, swelling and pain which accompany skin disorders, either of an acute or chronic nature.

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BACKGROUND OF THE INVENTION

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Many skin conditions, such as psoriasis, acne, poison ivy and heat rash to name only a few, are accompanied by an inflammation of the epithelium. This often leads to symptoms of burning, redness, itching, swelling and pain at the site. Although the root cause of the disorder varies with the disease, the generic inflammatory response is regulated by leukocyte activity and a host of inflammatory cytokines such as Interleukins and Tumor Necrosis Factors. Cell necrosis, as opposed to cell apoptosis, will release cellular debris into the extracellular environment in such a way as to activate neutrophils and macrophages, the key cells to initiate an inflammatory reaction. These activated cells themselves release a host of cytokines which chemotactically attract more leukocytes and other cells to the site of the inflammation. More information on inflammation, its causes, and its treatment may found in E. Arrigoni - Martelli *Inflammation and Antiinflammatories*, Spectrum Publication, 1977.

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In recent years bioactive glasses have been used for a wide variety of health related applications (see Hench, *et al.*, *Life Chemistry Reports*, vol. 13, pp 187 - 241 (1996)). Copending U.S. Patent application No. _____ teaches a pharmaceutical composition comprising non-linked particles of bioactive glass, optionally in a carrier which is suitable for topical application. This composition is taught to be useful for

promoting healing wounds and improving the structure and appearance of scar tissue as the wounds heal. However, there is no teaching that the composition could be used to reduce the symptoms of inflammation arising from skin disorders (other than wounds), such as allergic reactions and rashes.

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SUMMARY OF THE INVENTION

The present invention is a method for treating inflammatory symptoms related to various skin disorders other than wounds, comprising topical application of a non-interlinked, particulate bioactive glass mixed with a topical medicinal carrier to the site of the skin disorder.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As used herein the terms "bioactive glass" or "biologically active glass" mean an inorganic, glass material having an oxide of silicon as a major component and capable of bonding with growing tissue when reacted with physiological fluids. The term "skin disorder" means abnormalities, other than wounds, of the skin which have induced a state of inflammation. Such disorders include, but are not limited to warts, acme, dermatitis, hives, psoriasis, rashes, contact allergic reactions, and reactions to insect stings, and bites.

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The term "wound," as used herein, means an injury wherein the integrity of a patient's skin has been breached, as in the case of a cut or puncture, or where the skin has been destroyed by a chemical or thermal burn. "Normal" is used in the sense it is usually used in the medical arts. "Medical practitioner" means one of ordinary skill in the art of treating skin disorders. Typically this person is a physician, although in some cases, it may also be a nurse or physician's associate. The term "topical medicinal carrier" includes but is not limited to creams, ointments, gels, transdermal patches and lotions into which are blended therapeutic agents for topical application.,

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Particulate bioactive glasses in accordance with the present invention typically have the following composition by weight percentage:

5	Compound	percent range
	SiO_2	40-86
	CaO	10-46
	Na_2O	0-35
	P_2O_5	2-15
10	CaF_2	0-25
	B_2O_3	0-10
	K_2O	0-8
	MgO	0-5

wherein the total composition is 100%

The preferred composition of the bioactive glass for the present invention by weight percentage is:

Compound	Percent
SiO_2	45
CaO	24.5
Na_2O	24.5
P_2O_5	6

Bioactive glasses and methods of their preparation are well known in the art and several are commercially available.

Particulate, non-linked bioactive glass is preferred in the present invention. That is, the glass is in the form of small, discrete particles, rather than a fused matrix of particles or a fabric (woven or non-woven) of glass fibers. Note that under some conditions the discrete particles of the present invention may tend to cling together

because of electrostatic or other forces but are still considered to be non-linked.

The preferred particle size range for the bioactive glass is small and not greater than 90 microns. Particle sizes less than 20 microns as well as less than 2 microns can also be used. Particles of such a small size range generally provide for the advantages of the present invention but do not illicit any undesirable immune response.

There are many topical carriers known to those skilled in the art which may be used in the present invention, and the preferred carrier generally depends upon the specific disorder. The skilled artisans will appreciate that other therapeutic agents such as healing promotion agents, anti-inflammatory agents, antiseptic agents, and topical anesthetic agents may also be added to the composition of the present invention. Example of such agents include but are not limited to corticosteroids, benzocaine and lidocaine.

The bioactive glass and topical treatment can be combined in any pharmaceutically acceptable carrier to facilitate application to the skin. It is also within the scope of the present invention to combine the bioactive glass and topical ointment of the present invention with other treatments such as dressings, etc.

While not being bound to any particular theory or mechanism, the bioactive glass may also act as an absorbent of several inflammatory cytokines and thus act to shunt the overall inflammatory response in the area. Evidence indicates that reactivity of the bioactive glass releases ions into the extracellular environment which increases the extracellular osmotic pressure. This may reduce epithelial cell swelling and thus help prevent cell necrosis in the area,

Most preferably, particulate bioactive glass and the carrier are mixed just before application to the skin. If the two ingredients are mixed several days prior to application, e.g. one week, the ability of the composition to mitigate the inflammation

may be compromised. This problem is particularly acute, if the carrier causes bioactive glass to pre-react in a way that reduces the bioactivity of the glass.

While the ratio of bioactive glass to carrier is not critical, preferably the blend of bioactive glass, other therapeutic agents, and carrier contains about 20 % to about 80 % bioactive glass. The preferred particle size range for the bioactive glass is not greater about 90 microns is recommended. Particle sizes less than about 10 microns as well as less than about 2 microns can also be used. Particles of such a small size range generally provide for the advantages of the present invention but do not illicit any undesirable immune response. The proportion of other therapeutic agents varies according to the agent and the nature of the application. However, the preferred proportions are such that the amount of the agent administered to the area is in the dosage range approved by the accepted medical practice. The method of the present invention may be used on mammals, such as humans, and therefore is useful in both veterinary and well as human medicine.

The present invention is administered to a patient in a manner similar to that use for the administration of topical antiinflammatory compositions now in clinical use. While the exact treatment regimen is at the discretion of the attending medical practitioner, typical treatment comprises liberally applying a film of the bioactive glass containing composition to the inflamed area, optionally with gentle massage to work the composition into the skin. After application of the composition, the injured area is treated according to accepted medical practice, *e.g.*, after applying the composition, the injured area may be covered with a sterile bandage. Of course, in nonhuman mammals treatment would be in accordance with accepted veterinary practice, but would typically be analogous to human treatment.

Treatment frequency is not critical but is typically two to four time daily although supplemental applications may be needed if the patient is active and prone to a high rate of perspiration. Treatment is continued until the attending medical practitioner determines the symptoms of the inflammation are no longer present. A

patient being treated according to the method of the present invention may be concurrently treated with supplemental or adjuvant agents, such as oral or injected antiinflammatory or antibiotic agents.

EXAMPLES

Example 1

An individual suffering from psoriasis vulgaris and resulting prolonged inflammation on the arms was treated with a particulate bioactive glass known as "45S5" and having the preferred composition referenced herein above and having particle size of less than 20 microns blended into an aloe vera based gel. The ratio of bioactive glass to gel was 30 to 60 based on weight. These rashes were chronic and unsuccessfully treated prior to the treatment of this invention. The mixture of this invention was applied every 24 hours. After two treatments the itching, swelling and pain had ceased.

Example 2

An individual suffering for several years from psoriasis vulgaris on the palms of the hands was treated with a bioactive glass composition as used in Example 1. The rash was chronic and unresponsive to all other clinical treatments prior to the treatment of the present invention. The composition was applied once every 24 hours. After two treatments the itching, swelling and pain had ceased and redness was decreased.

Example 3

An individual suffering from a mildly chronic (18 month) skin rash on the top of the hand whose etiology was not determined was treated with a mixture of particulate bioactive glass composition described in Example 1. Previously, topical steroids alone were applied for 18 months with only moderate, transient success. The mixture of this invention was applied three times every 24 hours. After three treatments the rash had disappeared and did not recur.

What is claimed is:

1. A method of treating inflammatory symptoms related to skin disorders, other than wounds, in a mammal, comprising topical application to the site of the inflammatory skin disorder treating amount a topical medicinal composition comprising a non-interlinked, particulate bioactive glass mixed with a topical medicinal carrier.
2. The method of Claim 1 wherein the topical medicinal carrier is selected from the group consisting of topical creams, ointments, gels, and lotions.
3. The method of Claim 1 wherein the topical medicinal composition contains one or more additional therapeutic agents.
4. The method of Claim 3 wherein one or more therapeutic agents are selected from the group consisting of healing promotion agents, anti-inflammatory agents, antiseptic agents, and topical anesthetic agents.
5. The method of claim 1, wherein the bioactive glass has a composition range, by weight percentage as follows:

SiO ₂	40-86
CaO	10-46
Na ₂ O	0-35
P ₂ O ₅	2-15
CaF ₂	0-25
B ₂ O ₃	0-10
K ₂ O	0-8
MgO	0-5

wherein the total percentage is 100.

6. The method of claim 5, wherein the composition of the bioactive glass is:

Compound	Percent
SiO ₂	45
CaO	24.5
Na ₂ O	24.5
P ₂ O ₅	6

7. The method of claim 1, wherein the bioactive glass has a particle size range less than about 90 microns.

8. The method of claim 1, wherein the bioactive glass has a particle size range less than about 20 microns.

9. The method of claim 1, wherein the bioactive glass has a particle size range less than about 2 microns.

ABSTRACT

This invention relates to a method for treating inflammatory symptoms such as burning, redness, itching, swelling and pain which accompany skin disorders other than wounds of the skin. The method comprising topical application of a topical medicinal composition comprising a non-interlinked, particulate bioactive glass mixed with a topical medicinal carrier to the site of the skin disorder.

**COMBINED DECLARATION AND POWER OF ATTORNEY
FOR UTILITY PATENT APPLICATION**

Attorney's Docket No.

028870-080

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I BELIEVE I AM THE ORIGINAL, FIRST AND SOLE INVENTOR (if only one name is listed below) OR AN ORIGINAL, FIRST AND JOINT INVENTOR (if more than one name is listed below) OF THE SUBJECT MATTER WHICH IS CLAIMED AND FOR WHICH A PATENT IS SOUGHT ON THE INVENTION ENTITLED:

BIOACTIVE GLASS TREATMENT OF INFLAMMATION IN SKIN CONDITIONS

the specification of which

(check one)



is attached hereto;



was filed on _____ as

Application No. _____

and was amended on _____;
(if applicable)

I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE;

I ACKNOWLEDGE THE DUTY TO DISCLOSE TO THE OFFICE ALL INFORMATION KNOWN TO ME TO BE MATERIAL TO PATENTABILITY AS DEFINED IN TITLE 37, CODE OF FEDERAL REGULATIONS, Sec. 1.56 (as amended effective March 16, 1992);

I do not know and do not believe the said invention was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to said application; that said invention was not in public use or on sale in the United States of America more than one year prior to said application; that said invention has not been patented or made the subject of an inventor's certificate issued before the date of said application in any country foreign to the United States of America on any application filed by me or my legal representatives or assigns more than twelve months prior to said application;

I hereby claim foreign priority benefits under Title 35, United States Code Sec. 119 and/or Sec. 365 of any foreign application(s) for patent or inventor's certificate as indicated below and have also identified below any foreign application for patent or inventor's certificate on this invention having a filing date before that of the application(s) on which priority is claimed:

COMBINED DECLARATION AND POWER OF ATTORNEY	Attorney's Docket No. 028870-080
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COUNTRY/INTERNATIONAL	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED
			YES_ NO_
			YES_ NO_

William L. Mathis	17,337	Robert G. Mukai	28,531	Bruce J. Boggs, Jr.	32,344
Peter H. Smolka	15,913	George A. Hovanec, Jr.	28,223	William H. Benz	25,952
Robert S. Swecker	19,885	James A. LaBarre	28,632	Peter K. Skiff	31,917
Platon N. Mandros	22,124	E. Joseph Gess	28,510	Richard J. McGrath	29,195
Benton S. Duffett, Jr.	22,030	R. Danny Huntington	27,903	Matthew L. Schneider	32,814
Joseph R. Magnone	24,239	Eric H. Weisblatt	30,505	Michael G. Savage	32,596
Norman H. Stepno	22,716	James W. Peterson	26,057	Gerald F. Swiss	30,113
Ronald L. Grudziecki	24,970	Teresa Stanek Rea	30,427	Michael J. Ure	33,089
Frederick G. Michaud, Jr.	26,003	Robert E. Krebs	25,885	Charles F. Wieland III	33,096
Alan E. Kopecki	25,813	Robert M. Schulman	31,196	Bruce T. Wieder	33,815
Regis E. Slutter	26,999	William C. Rowland	30,888	Todd R. Walters	34,040
Samuel C. Miller, III	27,360	T. Gene Dillahunt	25,423		
Ralph L. Freeland, Jr.	16,110	Patrick C. Keane	32,858		


I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:

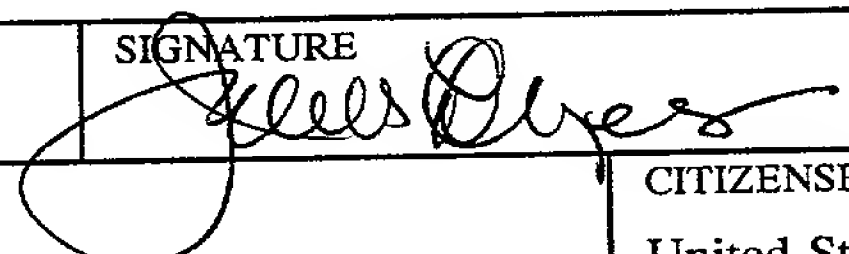
and: Allen R. Baum, Registration No. 36,086

Address all correspondence to: **Ronald L. Grudziecki**
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
 P.O. Box 1404
 Alexandria, Virginia 22313-1404

Address all telephone calls to: Allen R. Baum at (919) 941-9240.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF SOLE OR FIRST INVENTOR	SIGNATURE	DATE
Sean Lee		01/19/98
RESIDENCE		CITIZENSHIP
737 NW 84th Street		United States
POST OFFICE ADDRESS		
Gainesville, Florida 32607		
FULL NAME OF SECOND JOINT INVENTOR, IF ANY	SIGNATURE	DATE
James L. Meyers		
RESIDENCE		CITIZENSHIP
2610 NW 26th Place		United States
POST OFFICE ADDRESS		
Gainesville, Florida 32605		
FULL NAME OF THIRD JOINT INVENTOR, IF ANY	SIGNATURE	DATE
RESIDENCE		CITIZENSHIP

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<p>I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:</p> <p>and: <u>Allen R. Baum, Registration No. 36,086</u></p>																																																																																		
<p>Address all correspondence to: Ronald L. Grudziecki BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, Virginia 22313-1404</p>																																																																																		
<p>Address all telephone calls to: <u>Allen R. Baum</u> at (919) 941-9240.</p>																																																																																		
<p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p>																																																																																		
FULL NAME OF SOLE OR FIRST INVENTOR		SIGNATURE		DATE																																																																														
Sean Lee																																																																																		
RESIDENCE			CITIZENSHIP																																																																															
737 NW 84th Street			United States																																																																															
POST OFFICE ADDRESS																																																																																		
Gainesville, Florida 32607																																																																																		
FULL NAME OF SECOND JOINT INVENTOR, IF ANY		SIGNATURE		DATE																																																																														
James L. Meyers				1.11.98																																																																														
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2610 NW 26th Place			United States																																																																															
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FULL NAME OF THIRD JOINT INVENTOR, IF ANY		SIGNATURE		DATE																																																																														
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Patent
Attorney's Docket No. 028870-080

Applicant or Patentee: Sean Lee et al.

Application or Patent No.: _____

Filed or Issued: _____

For: BIOACTIVE GLASS TREATMENT OF INFLAMMATION IN SKIN CONDITIONS

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. §§ 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- ☒ the owner of the small business concern identified below;
☐ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN USBIOMATERIALS CORPORATION

ADDRESS OF CONCERN One Progress Boulevard, Box #23

Alachua, Florida 32615

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 C.F.R. § 121 for purposes of paying reduced fees under Sections 41(a) and 41(b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average, over the previous fiscal year of the concern, of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled BIOACTIVE GLASS TREATMENT OF INFLAMMATION IN SKIN CONDITIONS by inventor(s) Sean Lee and James L. Meyers described in

- ☒ the specification filed herewith
☐ Application No. _____, filed _____
☐ Patent No. _____, issued _____

If the rights held by the above-identified small business concern are not exclusive, each individual, concern, or organization having rights to the invention is listed below,* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 C.F.R. § 1.9(c), or by any concern that would not qualify as either a small business concern under 37 C.F.R. § 1.9(d) or a nonprofit organization under 37 C.F.R. § 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 C.F.R. § 1.27.)

Application Serial No. _____
Attorney's Docket No. 028870-080

NAME _____

ADDRESS _____

☐ individual ☐ small business concern ☐ nonprofit organization

NAME _____

ADDRESS _____

☐ individual ☐ small business concern ☐ nonprofit organization

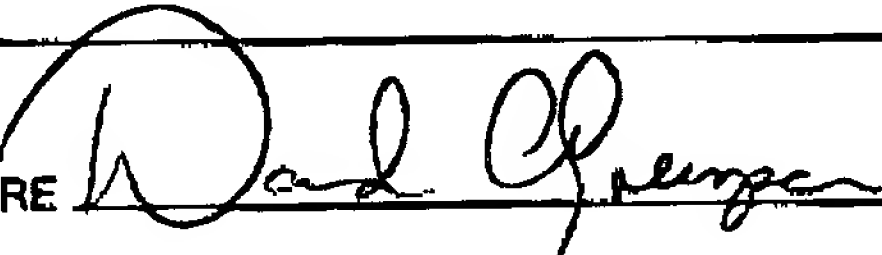
I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earlier of the issue fee and any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. § 1.28(b).)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING DAVID C GREENSPAN

TITLE OF PERSON OTHER THAN OWNER VICE PRESIDENT

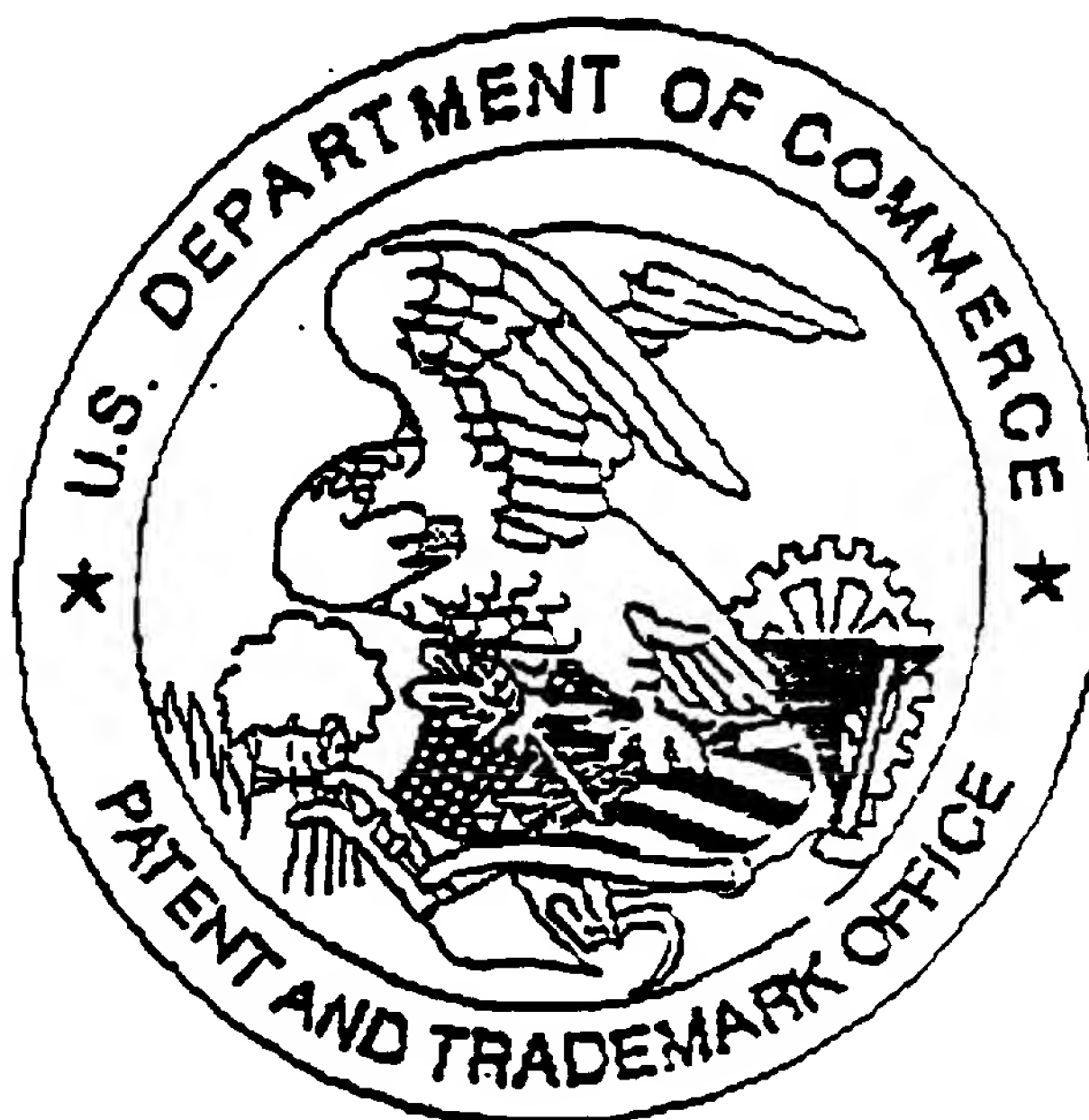
ADDRESS OF PERSON SIGNING _____

SIGNATURE  DATE 1/23/98

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